

Material Safety Data Sheet**Buprecare 0.3 mg/ml Solution for Injection****SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING****1.1 Product identification**

Product name(s):	Buprecare 0.3 mg/ml Solution for Injection
Product code(s):	XVD130 (1 ml ampoules) XVD190 (10 multidose vial)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses:	Veterinary medicinal product
Uses advised against:	Not for human use. Refer to the product information leaflet
Reasons why uses advised against:	Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name:	Animalcare Limited
Address:	10 Great Northway York Business Park Nether Poppleton York YO26 6RB United Kingdom

1.4 Emergency telephone number

Daytime:	+44 (0) 1904 487687
----------	---------------------

SECTION 2: HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) 1272/2008	This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.
---	--

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008	This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.
Hazard pictograms:	Not applicable
Signal word:	Not applicable
Hazard statements:	Not applicable
Precautionary statements:	Not applicable
Supplemental information:	Not applicable

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC)	None known
---	------------

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
Buprenorphine hydrochloride	[53152-21-9]	< 1%
Acetic acid	[64-19-7]	Proprietary
Ethyl alcohol	[200-578-6]	Proprietary
Glucose	[50-99-7]	Proprietary
Propylparaben	[94-13-3]	Proprietary
Methylparaben	[99-76-3]	Proprietary
Sodium acetate	[127-09-3]	Proprietary
Water	[7732-18-5]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately
Skin:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately
Inhalation:	Move to fresh air If discomfort occurs, get medical attention

4.2 Most important symptoms and effects, both acute and delayed

Short Term: Can cause eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain. May cause slight skin irritation. Vapours may cause drowsiness and dizziness. Breathing high vapor concentrations may cause central nervous system (CNS) depression resulting in dizziness, light headedness, headache, nausea and loss of coordination.

Long Term: Continued inhalation may result in unconsciousness and death. May have the potential to produce effects on the developing fetus.

Medical Conditions Aggravated by Exposure: None Known

See section 11 for more information on health effects and symptoms

4.3 Indication of any immediate medical attention and special treatment needed

No specific measures identified. Seek medical advice if required

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Extinguish fires with CO ₂ , extinguishing powder, foam or water
Unsuitable extinguishing media:	None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:	Flamable
Hazardous combustion products:	Decomposition products may include the following materials: Carbon oxides (CO _x), nitrogen oxides (NO _x). Fire/Explosion hazards: Flammable liquid and vapor. May present a fire hazard under fire conditions. May generate flammable vapours. Vapours are heavier than air and may travel along surfaces to remote ignition sources and flash back.

5.3 Advice for fire-fighters

Special protective equipment for firefighters:	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus
Further information:	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:	Ensure adequate ventilation
Advice for emergency responders:	Ground and bond containers when transferring material. Personnel must wear appropriate protective equipment (see section 8). Prevent exposure by any route

6.2 Environmental precautions

Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3 Methods and material for containment and cleaning up

Large spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel. Contain the source of the spill or leak and shut off all electrical equipment if it is safe to do so. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding procedures. Collect spill with a non-combustible absorbent material and transfer to labelled container for disposal. Clean spill area thoroughly. Prevent discharge to drains. Prevent runoff from entering waterways or sewers
Small spills:	Eliminate possible ignition sources (e.g. heat, sparks, flame, impact, friction, electricity) and follow appropriate grounding procedures. Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Prevent discharge to drains

6.4 Reference to other sections

See Section 1 for emergency contact information
See section 8 for personal protection
See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling:	Flammable. Keep away from heat, sparks, flame and all other sources of ignition. Take precautionary measures against static discharges. Ground and bond all bulk transfer equipment. Use only in a well-ventilated area. Restrict access to work area. Minimize generating airborne mists and vapours. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Avoid accidental injection. Releases to the environment should be avoided
Hygiene measures:	Wash thoroughly after handling

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:	Keep out of reach of children. Keep in the original packaging
Storage temperature:	Store below 25 °C. Do not refrigerate or freeze
Further information on storage conditions:	Keep away from heat and oxidizers, combustible materials

7.3 Specific end use(s)

For veterinary use only.

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. None known.

8.2 Exposure controls

Engineering measures: Good general ventilation should be sufficient to control worker exposure to airborne contaminants

Individual protection measures:

Hygiene measures: No specific measures identified

Eye/face protection: Safety glasses or goggles

Skin/body protection: Use protective clothing (uniforms, lab coats, disposable coveralls, etc) in both production and laboratory areas

Hand protection: Wear impervious gloves if skin contact is possible

Respiratory protection: Whenever air contamination (mist, vapor or odour) is generated, respiratory protection is recommended as a precaution to minimise exposure. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL

Environmental exposure controls: Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Liquid
Colour:	Colourless
Odour:	No data available
Odour threshold:	No data available
pH:	3.5 – 5.5
Density:	No data available
Melting point:	No data available
Boiling point:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability:	No data available
Water solubility:	Soluble
Partition coefficient:	4.98
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Explosive properties:	No data available
Oxidizing properties:	The substance or mixture is not classified as oxidizing

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Exposure to light. Exposure to sunlight. Keep away from heat and other sources of ignition, including electrostatic discharge

10.5 Incompatible materials

Heat and Oxidizers, combustible materials

10.6 Hazardous decomposition products

Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapours

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Buprenorphine hydrochloride LD ₅₀ >1000 mg/kg (Rat, oral) Buprenorphine hydrochloride LD ₅₀ 800 mg/kg (Mouse, oral) Buprenorphine hydrochloride LD ₅₀ 62 mg/kg (Rat, IV) Buprenorphine hydrochloride LD ₅₀ 72 mg/kg (Mouse, IV)
Chronic toxicity:	No data available
Skin irritation/sensitization:	No data available
Reproductive toxicity:	Buprenorphine hydrochloride NOAEL 80 mg/kg/day (Rat, negative fertility) Buprenorphine hydrochloride NOAEL 5 mg/kg/day IM (Rat, fetal development) Buprenorphine hydrochloride NOAEL 5 mg/kg/day IM (Rabbit, fetal development) Buprenorphine hydrochloride NOAEL 160 mg/kg/day (Rat, fetal development)
Carcinogenicity:	Buprenorphine hydrochloride NOAEL 56 mg/kg/day (Rat, Not carcinogenic) Buprenorphine hydrochloride NOAEL 100 mg/kg/day (Mouse, Not carcinogenic)
Mutagenicity:	Buprenorphine hydrochloride – Mammalian cell mutagenicity negative

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste of this product may qualify as a RCRA Hazardous Waste. Status should be confirmed by testing from RCRA hazardous characteristics (i.e. Corrosivity, toxicity, reactivity or ignitability).

Dispose of waste in accordance with all applicable laws and regulations. Member state specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

End of document